

REMARKS

This application pertains to novel solid lipid particles of bioactive agents and methods for the manufacture and use thereof.

Claims 1-40, 42, 44 and 45 are pending.

Claims 1-15 and 37-39 have withdrawn from consideration as drawn to non-elected subject-matter, so that the claims under consideration are claims 16 - 36, 40, 42, 44 and 45.

It is respectfully requested that upon allowance of claims drawn to elected subject matter the non-elected subject matter be rejoined.

Claim 16 has been amended to provide that the coating material E) is selected from the group consisting of partially hydrolyzed polyvinyl acetates, having a degree of hydrolysis of from 72 to 99 mol% and a viscosity of from 2 to 40 mPa.s. Support for this amendment can be found in the original specification, at page 12, line 31 - page 13, line 1. No new matter is added.

Claims 16-36, 40, 42 and 44-45 stand rejected under 35 U.S.C. 103(a) as obvious over Irvin (US 7,276,184) in view of Westesen et al. (US 5,885,486).

The technical effect achieved through the use of Applicants' novel pulverulent

active substances is the surprising finding discussed in the paragraph beginning on page 5, line 4 of the specification that "the pulverulent active substance formulations of the invention are substantially more stable than the existing preparations constitutionally closest to them, which are obtainable by melt dispersing, but in which the individual particles are not encapsulated.

Another reason for the unexpectedness of the stability of the formulations of the invention is that it would have been expected that the polyvinyl alcohol coat would dissolve in the water and that the active substance A) would then recrystallize. Contrary to these expectations, however, this effect did not occur."

Both Examples 1 and 2 (pages 26 and 27) of Applicants' specification employ "Mowiol 3-83" which (pursuant to page 12, line 26 - page 13, line 4) is a substance within the limitations of Applicants' claims, as amended, and which therefore enables achievement of the technical advantage mentioned above.

Considering the Irvin reference, there is a disclosure of "vinyl pyrrolidone (and) vinyl alcohols" as a CO₂ -phobic group (see col. 6, lines 45-54). However the Irvin reference fails to disclose partially hydrolyzed polyvinyl acetates.

These partially hydrolyzed polyvinyl acetates are a subgroup of the polyvinyl alcohols, but are distinct from "pure" polyvinyl-alcohols and as the selection of this "subgroup" forms a technical advantage, which also is not disclosed in the Irvin reference, there is no teaching or suggestion in the Irvin reference to use these as coating material.

With regard to the Westesen reference, there is no disclosure of "vinyl alcohols" at all in this reference. Therefore the further reading of the Westesen reference also does not render use of the aforementioned coating material obvious to one of ordinary skill in the art. Particularly as the Westesen reference uses a (coating material equivalent) matrix-material constituted by biocompatible **hydrophobic** materials which are solid at room temperature.

However, the more the polyvinyl acetates are "hydrolyzed" to become similar to "polyvinylalcohol" the more these substances become hydrophilic (i.e. soluble in water). Thus Applicants' partially hydrolyzed polyvinyl acetates, having a degree of hydrolysis of from 72 to 99 mol %, are by no means "hydrophobic".

To highlight this, Applicants enclose an IDS for the product brochure of Clariant, the manufacturer of Mowiol 3-83, and respectfully draw the Examiner's attention to page 13 of this document. Under the headline "Partially hydrolyzed« polyvinyl alcohols" explanation is given as to the dependency of the solubility of these partially hydrolyzed polyvinyl acetates in water on the degree of hydrolysis).

Accordingly, the selection of the particularly preferred coating material referred to above which is characterized by being partially hydrolyzed polyvinyl acetates, having a degree of hydrolysis of from 72 to 99 mol % and a viscosity of from 2 to 40 mPa s serves to enable an optimum between a polymeric, stable coat on the active substance and a prevention of recrystallization.

In view of the foregoing and further in view of the fact that neither the Irvin nor the Westesen reference teach or suggest usage of the above referred to coating material, the present application provides a novel step which is (indeed) unexpected.

Claim 42 stands rejected under 35 U.S.C. 103(a) as obvious over Irvin (US 7,276,184) in view of Westesen et al. (US 5,885,486) and further in view of Rochling et al. (US 6,602,823). The differences between Applicants' claims and anything that could be learned from the Irvin/Westesen references have been discussed above. There is nothing to be found in the Rochling reference that could possibly overcome these differences. The rejection of claim 42 under 35 U.S.C. 103(a) as obvious over Irvin (US 7,276,184) in view of Westesen et al. (US 5,885,486) and further in view of Rochling et al. (US 6,602,823) should therefore now be withdrawn.

In view of the present amendments and remarks it is believed that claims 1-40, 42, 44 and 45 are now in condition for allowance. Reconsideration of said claims by the Examiner is respectfully requested and the allowance thereof is courteously solicited.

CONDITIONAL PETITION FOR EXTENSION OF TIME

If any extension of time for this amendment is required, applicants request that this be considered a petition therefore. Please charge the required petition fee to Deposit Account No. 14-1263.

ADDITIONAL FEE

Please charge any insufficiency of fee or credit any excess to Deposit Account No. 14-1263.

Respectfully submitted,
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